Title

Bayer CropScience Comments on Imidacloprid Registration Review

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March 9, 2009
Date

STATEMENT OF COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

Information in this document summarizes technical data submitted in support of registration or provides risk assessments using these data and is not subject to Good Laboratory Practice Standards.

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Bayer CropScience Comments on Imidacloprid Registration Review

Introduction

Bayer CropScience would like to thank EPA for compiling the various documents in preparation for Registration Review for Imidacloprid. We would also like to thank the Agency for the opportunity to comment on these documents.

Bayer CropScience provides comments below on the following documents:

- Imidacloprid Summary Document (Document No. EPA-HQ-OPP-2008-0844-002)
- Problem Formulation For The Imidacloprid Environmental Fate And Ecological Risk Assessment (Document No. EPA-HQ-OPP-2008-0844-003)

Specific Comments on EPA-HQ-OPP-2008-0844-002: Imidacloprid Summary Document:

EPA Summary Document: Page 4. List of study requirements

- EPA Requirement: **Field Test for pollinators** and **Repeat dose field testing for pollinators**
    - BCS Comments: BCS is supplying a number of published papers and unpublished studies which address these issues, and may fulfill some of these requirements. See "**Appendix 1 Imidacloprid and Bees: A Summary of Published Literature and Unpublished Reports**"
- EPA Requirement: **Tier 1 Seedling emergence study (Tier 1) using TEP** and **Tier 1 Vegetative Vigor**
    - BCS Comments: BCS recognizes that this is a requirement for pesticide registration. However, given the very extensive use of imidacloprid on a wide variety of crops over many years, and the very small numbers of reported incidents, BCS questions whether this will add significant value to the risk assessment.
- EPA Requirement: **Seed leaching study using TEP imidacloprid**
    - BCS Comments: The mobility of imidacloprid in soil has been extensively evaluated. Many of the studies were previously submitted to the Agency. Mobility studies not previously submitted to the Agency are given in Appendix 5.

EPA Summary Document: EPA Comments

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- EPA Comment: **"The planned ecological risk assessment will allow the Agency to determine whether imidacloprid's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats.........."**

  - BCS Response: This document and the EFED problem formulation document state that the Agency is interested in receiving information on use history, use rates and patterns for all formulations containing imidacloprid at county and sub-county levels. Additionally, other relevant information for an endangered species assessment can also be provided. BCS will endeavor to provide the relevant information to the extent possible in a timely manner, and would request an opportunity to meet with EPA to discuss when and how best this information can be provided. However, since the use patterns are continuing to change and data sources for this type of information continue to evolve, the timing for obtaining the information is crucial for the relevance of the data.

  - BCS is also providing additional higher tier studies on birds, bees and aquatic organisms which may be useful in further refining the risk assessments for endangered and non-endangered species.
  - See **Appendix 2; Additional studies for risk assessment.**

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- EPA Comment: **"Stakeholders are also specifically asked to provide information and data that will assist the agency in refining its ecological risk assessment"**

  - BCS Response: See note above – BCS is submitting a number of additional studies on honeybees.

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- EPA Comment: **'Imidacloprid has the potential to cause chronic risk to avian species and small mammals................"**

  - BCS Response: BCS believes that the risk to birds and mammals may have been overestimated. It appears that the EPA has used the 'default' foliar half-life of 35 days in their calculations of exposure to food items for birds and mammals. BCS believes that this will result in a significant over-exposure, since imidacloprid declines rather rapidly in sunlight. Several reports have been previously submitted to the Agency which support the use of a much shorter half-life. These are listed below:

  Turf:

  42256307 Lin, J. (1992) Evaluation of the Foliar Half-life and Distribution of NTN-33893 in Turf: Lab Project Number: N3022701: 102605. Unpublished study prepared by Miles Inc.

164 p.

Soybeans (decline trial on foliage):

46785002 Mackie, S. (2005) Trimax 4F - Magnitude of the Residue on Soybeans. Project Number: NT001/04D, NT002/04H, NT003/04H. Unpublished study prepared by Bayer Corp., Bayer Research Farm and Ashgrow Crop Management Systems, Inc. 307 p.

Potato Leaves:

42556101 Lin, J. (1992) Evaluation of the Foliar Half-life and Distribution of NTN 33893 in Potatoes: Lab Project Number: N319P003: 103233. Unpublished study prepared by Miles Inc. and ABC Labs. 166 p.

Lettuce:

42810307 Burger, R.; Lenz, C. (1993) Imidacloprid (2.5GR & 2F)--Magnitude of the Residue on Lettuce: Lab Project Number: N319LE01: N319LE02: N319LE03. Unpublished study prepared by Miles Inc. 2210 p.

Cabbage:

42810306 Lenz, C.; Burger, R. (1993) Imidacloprid (2.5GR & 2F)--Magnitude of the Residue on Cabbage: Lab Project Number: N319CB01: N319CB02: N319CB03. Unpublished study prepared by Miles Inc. 1258 p.

In addition, as mentioned above, BCS has conducted a number of studies to refine the risk assessment for birds and mammals. See Appendix 2; Additional studies for risk assessment.

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- EPA Comment: **"Secondary toxicity to fish is also possible through alteration of the food chains based on invertebrates."**

    - BCS Response: The literature on imidacloprid and aquatic invertebrates is very rich, and there is great variability in effects on different invertebrate species. For this reason, BCS recommends the use of a 'Species Sensitivity Distribution' (SSD) or other probabilistic approach to more accurately assess the risk to invertebrates, and thus the indirect risk to fish. BCS is also submitting a microcosm study, and an associated independent review of the microcosm findings. (see Appendix 2; Additional studies for risk assessment.)

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- EPA Comment: "**EPA expects to require data to evaluate sublethal effects to bees and other beneficial insects.........**"

    - BCS Response: A number of studies on beneficial insects were performed in Europe. These do not normally form part of the US submission, but a list is being provided (Appendix 3) and actual study reports can be provided on request.

Specific Comments on EPA-HQ-OPP-2008-0844-003: Imidacloprid Problem Formulation Document:

- EPA Comment: **"Since parent imidacloprid is environmentally persistent, these degradates are more likely to be found in ground water than surface water because of the usually much longer travel times to ground water."**

  BCS Response: Imidacloprid has been widely used in the USA since registration in 1994. This pesticide is used for the control of sucking insects including rice hoppers, aphids, thrips, and whiteflies, as well as for control of termites, turf insects, soil insects, tree pests and some beetles. With the widespread use of this compound, this pesticide has been included in numerous surface and ground water monitoring efforts at county, state and federal levels. In various monitoring programs, over 12,000 water samples have been analyzed for imidacloprid. Detections of imidacloprid above the limit of quantitation (LOQ) (LOQ ranged between 0.0068 and 0.5 µg/L or ppb) are infrequent even in areas that would be considered vulnerable with regard to potential for movement to surface or ground waters. When samples with notable concentrations are identified, they have generally been found in highly vulnerable areas or were associated with point-source issues.

  In no case has levels of imidacloprid in potential drinking waters approached any level of concern for human health. An unofficial maximum contaminant level communicated to Bayer CropScience is 525 µg/L (EPA letter to BCS, 1993). Upon further evaluation of the toxicological endpoint used in this calculation, BCS recalculated a more conservative number of 399 µg/L. More recently, EPA calculated a Drinking Water Level of Concern (DWLOC) in 2003 of 510 µg/L (for children 1 to 2 years old) (Federal Register: June 13, 2003 (Volume 68, Number 114), below which there is reasonable certainty of no human health concern as part of an overall dietary assessment.

  - From an ecological perspective, results from over 2,000 water samples tested by a range of organizations were examined. The maximum concentration reported in surface water should not pose any significant risk to fresh water, non-target aquatic organisms based on acute toxicity. Imidacloprid has a short half-life in water exposed to sunlight (< 4 hours), so significant concentrations of imidacloprid would not be expected in surface water. See Appendix 4 for more details.

Appendix 1

Imidacloprid and Bees: A Summary of Published Literature and Unpublished Reports

EPA has indicated that they will be reviewing available literature for imidacloprid effects on bees. BCS is providing a number of relevant publications and reports – a brief summary is attached.

1. Toxicity

1.1 Acute:

EPA has previously received and reviewed the acute toxicity studies (oral and contact, Guideline 850.3020, Cole (1990) and the bee residue test (Guideline 850.3030, Hancock et al. 1992). Other relevant information on acute toxicity of imidacloprid and metabolites is presented in Schmuck and Schoening, (1999a) and Schmuck et al (2003).

NOTE: For oral toxicity, it is useful to convert lethal dose (LD_{50}) values which are expressed in units of micrograms per bee to an equivalent food concentration (LC_{50}) expressed in parts per billion (ppb). This provides a benchmark for comparison to concentrations that might be analytically measured in bee foods (pollen, nectar). To make this conversion, one simply divides by the amount of sucrose solution ingested by a bee in an LD_{50} test (26 mg) and then multiplies by 1 million (to convert the answer from parts per thousand to parts per billion).

$LC_{50} = (y / 26) \cdot 1{,}000{,}000$

For imidacloprid, y, the lowest measured LD_{50} is 0.0039 µg/bee, so the LC50 would be 150 ppb.

1.2 Chronic

Long-term (chronic) exposures do NOT represent a significantly greater risk than acute exposures because neonicotinoids are rapidly metabolized and do not bio-accumulate. (Suchail et al. (2003)).

A study was published that claimed chronic toxic effects in honey bees at very low exposure levels of imidacloprid (Suchail 2001). However, subsequent research indicates that these highly unusual findings were probably erroneous. This study reported no difference in chronic toxicity between those metabolites in which the toxophore was intact and those in which it was cleaved off. Similar levels of mortality were seen with doses ranging across two orders of magnitude. Four other laboratories were unable to reproduce these findings (Schmuck, 2004). The chronic, No Adverse Effect Concentration (NOAEC) for imidacloprid (derived from extensive field and semi-field testing – see below) is in the range of 20 parts per billion.

1.3 'Sub-lethal' effects

Several papers have been published on effects referred to as 'sub-lethal' (although many of these studies were carried out at concentrations or doses likely to result in lethality). Effects on learning and memory have been carried out based on a 'conditioned response' paradigm (Proboscis Extension Reflex) first described by Bitterman et al. (1983). These have yielded variable results, but report thresholds for impairment of learning performance to be in the range of 12 to 100 ppb. (Decourtye et al. (2003a), Decourtye et al. (2003b), Kirchner (1998)). Interestingly a study by Lambin et al. (2001) indicated that low doses of imidacloprid actually improved learning performance.

Investigations on learning and memory have also been conducted under field conditions. In studies in which bees were trained to use artificial feeders located up to 500 m from the hive, the orientation behavior of bees was unaffected when the concentration was 10 ppb and 20 ppb, slightly affected with no overall damage to the colony when the concentration was 50 or 100 ppb, and severely affected (most bees not returning to the colony) when the concentration was 500 or 1000 ppb (Bortolotti et al. 2003). At these higher concentrations, lethal effects are likely to have occurred.

Other sub-lethal effects studied include effects on foraging, and on bee communication via dancing. Kirchner (1998, 1999) found a dose-related increase in tremble dances in worker bees returning from feeding on sucrose solutions spiked with 20-100 ppb imidacloprid. Recruitment of new foragers and visitation to the feeder was reduced when the concentration was 50 and 100 ppb, but not at 10 or 20 ppb. Several studies (Colin et al. (2004), Ramirez-Romero (2007)) have indicated that bees can detect imidacloprid at low levels, and this may repel feeding. This is not necessarily an adverse effect.

A recent paper (Yang et al. 2008) investigated the effect of imidacloprid on foraging behavior. Their investigation indicated dose-dependent effects on foraging, with significant effects at concentrations of 600 ppb and above. Concentrations up to 50 ppb had no effect on foraging activity.

<u>References for Section 1: Toxicity</u>:

Studies in bold type are being submitted with these comments.

Other studies (with MRID numbers) have previously been submitted to EPA.

Author	Date	Citation	MRID
Bitterman, M. E.; Menzel, R.; Fietz, A.; Schäfer, S.	**1983**	**Classical conditioning of proboscis extension in honeybees (Apis mellifera). Journal of Comparative Psychology; 97 (2), 107-119 (See also Bayer Document No.: M-110140-01-2; February 10, 2009)**	Included with this submission
Bortolotti, L., Montanari, R., Marcelino, J., Medrzycki, P., Maini, S., Porrini, C.	**2003**	**Effects of sub-lethal imidacloprid doses on the homing rate and foraging activity of honey bees. Bulletin of Insectology 56 (1): 63-67, (See also Bayer Document No.: M-329656-01-1; December 31, 2003)**	Included with this submission
Cole,J.	1990	The Acute Oral and Contact Toxicity to Honey Bees of Compound NTN 33893 Technical: Lab Project Number: 101321. Unpublished study prepared by RCC, Research and Consulting Company AG. 13 p	42273003

Colin, M.; Bonmatin, J.; Moineau, I.; et al.	2004	A Method to Quantify and Analyze the Foraging Activity of Honey Bees: Relevance to the Sublethal Effects Induced by Systemic Insecticides. Archives of Environmental Contamination and Toxicology 47: 387-395.	47523408
Decourtye, A.; Armengaud, C.; Renou, M.; et al.	2003a	Imidacloprid Impairs Memory and Brain Metabolism in the Honeybee (Apis mellifera L.). Pesticide Biochemistry and Physiology 78: 83-92.	47523405
Decourtyle, A.; Lacassie, E.; Phan-Delegue, M.	2003b	Learning Performances on Honeybees (Apis mellifera L) are Differentially Affected by Imidacloprid According to the Season. Pest Management Science 59: 269-278.	47523410
Hancock, G.; Fischer, D.; Mayer, D.; et al.	1992	NTN 33893: Toxicity to Honey Bees on Alfalfa Treated Foliage: Lab Project Number: N3772902: 103938. Unpublished study prepared by Washington State University and Miles Residue Analysis Lab. 62p.	42632901
Kirchner, W. H.	**1999**	**Mad-bee-disease? Sublethal effects of imidacloprid (Gaucho) on the behaviour of honeybees. Apidologie 30: 421-422 (See also Bayer Document No.: M-329657-01-1; December 31, 1999)**	Included with this submission
Kirchner, W.H.	**1998**	**The effects of sublethal doses of imidacloprid on the foraging behaviour and orientation ability of honeybees. Bayer Report Number: M-074400-01-1 (See also Bayer Document No.: M-074400-01-3)**	Included with this submission
Kirchner, W.H.	**2000**	**The effects of sublethal doses of imidacloprid, hydroxy-imidacloprid and olefine-imidacloprid on the behaviour of honeybees. Bayer Report Number: M-031852-02-1 (See also Bayer Document No.: M-031852-02-2.)**	Included with this submission
Lambin, M.; Armengaud, C.; Raymond, S.; Gauthier, M. (2001):	**2001**	**Imidacloprid-Induced Facilitation of the Proboscis Extension Reflex Habituation in the Honeybee. Archives of Insect Biochemistry and Physiology; 48, 129-134. (See also Bayer Document No.: M-111240-01-2; February 10, 2009)**	Included with this submission

Ramirez-Romero, R., Chaufaux, J.,Pham-Delegue,M.	**2005**	**Effects of Cry1Ab Protoxin, Deltamethrin and Imidacloprid on the Foraging Activity and the Learning Performances of the Honeybee Apis mellifera, a Comparative Approach. Apidologie 36(4):601-611 (See also Bayer Document No.: M-341229-01-1; March 04, 2009)**	Included with this submission
Schmuck, R. (2004):.	**2004**	**Effects of a Chronic Dietary Exposure of the Honeybee Apis mellifera (Hymenoptera: Apidae) to Imidacloprid. Archives of Environmental Contamination and Toxicology; 47 (4), 471-478. (See also Bayer Document No.: M-329662-01-1; December 31, 2004)**	Included with this submission
Schmuck, R., Nauen, R., Ebbinghaus-Kintscher, U. (2003):	**2003**	**Effects of imidacloprid and common plant metabolites of imidacloprid in the honeybee: toxicological and biochemical considerations. Bulletin of Insectology 56 (1): 27-34. (See also Bayer Document No.: M-329663-01-1; December 31, 2003)**	Included with this submission
Schmuck, R.; Schoening, R	**1999a**	**Residue levels of imidacloprid and imidacloprid metabolites in honeybees orally dosed with imidacloprid in standardized toxicity tests (EPPO 170) Bayer Report Number: M-017079-01-1**	Included with this submission
Suchail, S.; Debrauwer, L.; Belzunces, L.	2003	Metabolism of Imidacloprid in Apis mellifera. Pest Management Science 60: 291-296.	47523409
Suchail, S.; Guez, D.; Belzunces, L.	2001	Discrepancy Between Acute and Chronic Toxicity Induced by Imidacloprid and its Metabolites in Apis mellifera. Environmental Toxicology and Chemistry 20 (11) : 2482-2486.	47523402
Yang, E.C., Chuang, Y.C., Chen, Y.L. and L.H. Chang	**2008**	**Abnormal foraging behavior induced by sublethal dosage of imidacloprid in the honey bee (Hymenoptera: Apidae). J. Econ. Entomol. 101(6): 1743-1748 (See also Bayer Document No.: M-337550-01-1; March 03, 2009)**	Included with this submission

2. Exposure

2.1 Routes of Exposure

Honey bees could be exposed to imidacloprid in two general ways:

(1) to residues deposited on flowers or foliage by foliar sprays; and

(2) to residues taken up systemically by plants and translocated into nectar and pollen in the flowers.

Exposure via the first route should be minimal for imidacloprid because the product labels restrict foliar applications to plants that are not in bloom. With respect to exposure to systemic residues, research has shown that imidacloprid enters the xylem (water transport system in the plant) and moves very rapidly upwards into the leaves to provide protection against insect damage. Transport back to other parts of the plant, including the flowers, can only take place via the phloem, and studies show that very little imidacloprid is transported this way. (Sur and Stork 2003).

2.2 Measurement of Residues

Extensive measurements of residues in pollen and nectar of bee attractive plants have been carried out. BCS field studies are summarized in Maus et al. (2003) and data for individual crops can be found in the following reports (these reports are included in the reference list on page 12):

Corn: M-052637-01-1 Maus, C.; Schoening, R. (2001); , M-052238-01-1 Maus, C. (2002) M-016845-01-1 Schmuck, R.; Schoening, R. (1999);, M-016836-01-1 Schmuck, R.; Schoening, R.; Schramel, O. (1999a), M-016830-01-1 Schmuck, R.; Schoening, R.; Schramel, O. (1999b)

Rape: M-006811-01-1 Schmuck, R.; Schoening, R. (1999c), M-052524-02-1 Schoening, R. (2002), M-016828-02-1 Schmuck, R.; Schoening, R.; Schramel, O. (2007), M-006815-01-1 Schmuck, R.; Schoening, R. (1999d), Scott-Dupree et al, (2001)

Sunflower: M-016832-01-1 Schmuck, R.; Schoening, R. (1999e), M-016827-01-1 Schmuck, R.; Schoening, R.; Schramel, O. (1999c), M-016820-01-1 Schmuck, R.; Schoening, R.; Schramel, O. (1999).

Clover, planted in fields previously planted with potatoes, M-061850-01-1, Kemp and Rogers (2002).

Several independent scientists have also measured residue levels in pollen. Bonmatin et al. (2005) reported average levels of 2.1 ppb in corn pollen in France, and Chauzat et al. (2006) reported residue levels of 1.1 to 5.7 ppb in pollen in apiaries in France.

Studies referenced on p.10 of the EFED problem formulation (EPA-HQ-OPP-2008-0844-003) have shown that certain shrubs and woody plants can occasionally contain residues in flowers significantly higher than those seen in crop plants. A study on the effects of bees exposed to these plants (Maus et al. 2006, 2007) indicated that while these plants might pose a slight risk to individual forager bees, the colonies were not adversely affected.

References for Section 2: Exposure

Studies in bold type are being submitted with these comments.

Other studies (with MRID numbers) have previously been submitted to EPA.

Author	Date	Citation	MRID
Bonmatin, J.; Marchand, P.; Charvet, R.; etal.	2005	Quantification of Imidacloprid Uptake in Maize Crops. Journal of Agricultural and Food Chemistry 53: 5336-5341.	47523411
Chauzat, M.; Faucon, J.; Martel, A.; et al.	2005	A Survey of Pesticide Residues in Pollen Loads Collected by Honey Bees In France. Entomological Society of America 99(2): 253-262.	47523403
Kemp, J:, Rogers,R.	**2002**	**Imidacloprid (Admire®) Residue Levels Following In-furrow Application in Potato Fields in Prince Edward Island and New Brunswick Bayer Report Number: M-061850-01-1**	Included with this submission
Maus, C.	**2002**	**Evaluation of the effects of residues of imidacloprid FS 600 in maize pollen from dressed seeds on honeybees (Apis mellifera) in the semifield Bayer Report Number: M-052238-01-1 (See also Bayer Document No.: M-052238-01-2; February 24, 2009)**	Included with this submission
Maus, C., Curé, G and Schmuck, R. (2003):	**2003**	**Safety of imidacloprid seed dressings to honey bees: a comprehensive overview and compilation of the current state of knowledge, Bulletin of Insectology 56 (1): 51-58. (See also Bayer Document No.: M-329659-01-1; December 31, 2003)**	Included with this submission
Maus, C.; Schoening, R.	**2001**	**Effects of residues of imidacloprid in maize pollen from dressed seeds on honey bees (Apis mellifera). Bayer Report Number: M-052637-01-1 (See also Bayer Document No.: M-052637-01-2; February 24, 2009)**	Included with this submission
Maus, C.; Schoening, R.; Doering, J.	2006	Assessment of Effects of Imidacloprid WG 70 on Foraging Activity and Mortality of Honey Bees and Bumblebees after Drenching Application under Field Conditions on Shrubs of the Species Rhododendron catabiense grandiflorum Surrounded by other. Project Number: G201808, P672054701 Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer CropScience. 25p.	47303405

Maus, C.; Schoening, R.; Doering, J.	2007	Assessment of Effects of a Drench Application of Imidacloprid WG 70 to Shrubs of Rhododendron sp. and to Hibiscus syriacus on Foraging Activity and Mortality of Honeybees and Bumblebees Under Field Conditions. Project Number: P672064704, G201809. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer CropScience. 45 p.	47303406
Schmuck, R.; Schoening, R	**1999b**	**Effects of imidacloprid residues in maize pollen on the development of small bee colonies under field exposure conditions. Bayer Report Number: M-016845-01-1**	Included with this submission
Schmuck, R.; Schoening, R.	**1999c**	**Residues of imidacloprid and imidacloprid metabolites in nectar, blossoms, pollen and honey bees sampled from a summer rape field in Sweden and effects of these residues on foraging honeybees. Bayer Report Number: M-006811-01-1**	Included with this submission
Schmuck, R.; Schoening, R.	**1999d**	**Residues of imidacloprid and imidacloprid metabolites in nectar, blossoms, pollen and honey bees sampled from a French summer rape field and effects of these residues on foraging honeybees. Bayer Report Number: M-006815-01-1**	Included with this submission
Schmuck, R.; Schoening, R.	**1999e**	**Effects of imidacloprid residues in sunflower honey on the development of small bee colonies under field exposure conditions. Bayer Report Number: M-016832-01-1**	Included with this submission
Schmuck, R.; Schoening, R.; Schramel, O.	**1999d**	**Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of sunflowers cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. 'Hoefchen' 1999. Bayer Report Number: M-016820-01-1 (See also Bayer Document No.: M-016820-01-2)**	Included with this submission
Schmuck, R.; Schoening, R.; Schramel, O.	**1999e**	**Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of sunflowers cultivated on soils with different imidacloprid residue levels and effects on these residues on foraging honeybees. 'Laacher Hof' 1999. Bayer Report Number: M-016827-01-1 (See also Bayer Document No.: M-016827-01-2)**	Included with this submission

Schmuck, R.; Schoening, R.; Schramel, O.	**1999a**	**Residue levels of imidacloprid and imidacloprid metabolites in pollen of maize plants cultivated on soils with different imidacloprid residue levels. Test location: farmland 'Laacher Hof' - 1999. Bayer Report Number: M-016836-01-1 (See also Bayer Document No.: M-016836-01-2)**	Included with this submission
Schmuck, R.; Schoening, R.; Schramel, O.	**1999b**	**Residue levels of imidacloprid and imidacloprid metabolites in pollen of maize plants cultivated on soils with different imidacloprid residue levels Test location: farmland 'Hoefchen' - 1999. Bayer Report Number: M-016830-01-1 (See also Bayer Document No.: M-016830-01-2**	Included with this submission
Schmuck, R.; Schoening, R.; Schramel, O.	**1999c, amended 2007**	**Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. Laacher Hof 1999. Bayer Report Number: M-016828-02-1 (See also Bayer Document No.: M-016828-02-2)**	Included with this submission
Schoening, R.	**2002**	**Determination of residues of imidacloprid and relevant metabolites in nectar, pollen and honey of winter rape. Bayer Report Number: M-052524-02-1 (See also Bayer Document No.: M-052524-02-2; February 23, 2009)**	Included with this submission
Scott-Dupree, C.D., Spivak, M.S., Bruns, G., Blenkinsop, C., Nelson,S.	2001	The impact of Gaucho® and TI-435 seed treated canola on honey bees (*Apis mellifera* L.) Bayer Study Number: M-084721-01-1	45422435
Sur, E.; Stork, A.	**2003**	**Uptake, translocation and metabolism of imidacloprid in plants. Bulletin of Insectology 56 (1): 35-40 (See also Bayer Document No.: M-110763-01-2; January 01, 2003)**	Included with this submission

3. Field Studies and Risk Assessments

Many of the residue measurements cited above were carried out as part of field or semi-field studies with honeybee colonies. These studies included detailed measurement of honey bee mortality, foraging, brood development and hive health. None of the studies gave any indication of harm to honeybee colonies despite prolonged exposure to imidacloprid-treated crops and Maus et al. (2003). The risk to sunflowers was reviewed in Schmuck (1999), Schmuck et al.

(2001) . An additional USDA study on cantaloupes investigated potential effects of imidacloprid on bees used for pollination, and concluded that imidacloprid applied according to normal agricultural practice had no harmful effect on bees (Elzen et al., 2004).

Several publications have addressed the potential risk from imidacloprid to honeybees from agricultural uses. A French Risk Assessment produced by the Comité Scientifique et Technique in France (Doucet-Personeni, Halm and Touffet (2004) is attached, together with reviews of the methodology and conclusions by two independent researchers, Dr. H. Thompson and Dr. W. Kirchner. (Thompson, 2004, Kirchner, 2004) These researchers were highly critical of the methods used in the French Risk Assessment. The potential risk estimated by the CST is not borne out by the many field studies showing no effect of imidacloprid-treated crops on bee colonies.

A USDA funded study on honeybees and imidacloprid is in progress.

The studies listed above were all carried out with honeybees. However, three studies have addressed the risk to bumble bees. Morandin et al. (2003) concluded that there were no measurable effects on bumble bee colony or individual bee health from exposure to imidacloprid at concentrations similar to and above the highest residue levels found in pollen. Tasei et al. (2001) concluded applying imidacloprid at the registered dose, as a seed coating of sunflowers cultivated in greenhouse or in field, did not significantly affect the foraging and homing behavior of *B. terrestris* and its colony development. Gels and Potter (2002) demonstrated that watered-in granular formulations of imidacloprid had no significant effects on bumble bee colonies.

<u>**References for Section 3: Field Studies and Risk Assessments**</u>

Studies in bold type are being submitted with these comments.

Other studies (with MRID numbers) have previously been submitted to EPA.

Author	Date	Citation	MRID
Doucet-Personeni,C; Halm,M.P.;Touffet, F.	**2003**	**Imidacloprid used as a Seed Dressing (Gaucho) and Disorders in Bees – Translation of Report "Imidaclopride utilisé en enrobage de semences (Gaucho) et troubles des abeilles-Rapport final (See also Bayer Document No.: M-330584-01-1; September 18, 2003)**	Included with this submission
Elzen, P.J.,Elzen, G.W. ,Lester, G.E.	**2004**	**Compatibility of an Organically Based Insect Control Program with Honey Bee (Hymenoptera: Apidae) Pollination in Cantaloupes. J.Econ.Entomol. 97(5):1513-1516 (See also Bayer Document No.: M-341249-01-1; January 01, 2004)**	Included with this submission
Gels, J.A.; Held, D.W.; Potter, D.A	**2002**	**Hazards of Insecticides to the Bumble Bees Bombus impatiens (Hymenoptera Apidae) Foraging on Flowering Clover in Turf Journal of Economic**	Included with this submission

		Entomology; 95 (4), 722-728 (See also Bayer Document No.: M-210591-01-2; January 01, 2002)	
Kirchner, W.H.	**2004**	**Evaluation of the possible effects of imidacloprid used as a seed dressing on honeybees. It was reported by the Comite Scientifique et Technique de L'Etude Multifactorielle des Troubles des Abeilles (Imidaclopride utilise en enrobage de semences (Gaucho) et troubles des abeilles). Unpublished report. (See also Bayer Document No.: M-337643-01-1; December 31, 2004)**	Included with this submission
Morandin, L. A.; Winston, M. L.	**2003**	**Effects of Novel Pesticides on Bumble Bee (Hymenoptera: Apidae) Colony Health and Foraging Ability. Enviromental Entomology; 32 (3), 555-563 (See also Bayer Document No.: M-329660-01-1; December 31, 2003)**	Included with this submission
Schmuck, R. (1999):	**1999**	**No causal relationship between Gaucho seed dressing in sunflowers and the French bee syndrome. Pflanzenschutz-Nachrichten Bayer; 52 (3), 267-309. (See also Bayer Document No.: M-110451-01-3; January 01, 1999)**	Included with this submission
Schmuck, R.; Schoening, R.; Stork, A.; Schramel O.	**2001**	**Risk posed to honeybees (Apis mellifera L., Hymenoptera) by an imidacloprid seed dressing of sunflowers. Pest Management Science; 57 (3), 225-238 (See also Bayer Document No.: M-258800-01-2; January 01, 2001)**	Included with this submission
Tasei, J. N.; Ripault, G.; Rivault, E.	**2001**	**Hazards of Imidacloprid Seed Coating to Bombus terrestris (Hymenoptera: Aphidae) When Applied to Sunflower., Journal of Economic Entomology; 94 (3), 623-627 (See also Bayer Document No.: M-000571-01-2; January 01, 2001)**	Included with this submission
Thompson, H.M.	**2004**	**Expert Opinion: Risk Assessment for Systemic Pesticides and Honeybees. Review of the approach taken by the Scientific and Technical Committee responsible for the multi-factorial study of disorders in bees (CST), Unpublished Report (See also Bayer Document No.: M-089690-01-2; February 26, 200)**	Included with this submission

4. Studies to investigate mixtures of imidacloprid with fungicides

Recent reports have suggested an interaction between fungicides and neonicotinoids. A paper by Iwasa et al (2003) demonstrated that certain azole fungicides synergize the toxicity of the cyanoamidine subclass of neonicotinoid compounds (acetamiprid and thiacloprid). These compounds are relatively non-toxic to honey bees because the bees have enzymes that break them down quickly to non-toxic byproducts. However, the presence of azole fungicides appears to block the activity of these detoxifying enzymes. The result is these compounds become much more toxic (but not more toxic than nitroguanidines) when the bee has also been exposed to the fungicide. This synergistic effect has only been demonstrated to occur under highly artificial laboratory conditions, and the study clearly demonstrated that the fungicides did not synergize the action of imidacloprid.

Iwasa, T.; Motoyama, N.; Ambrose, J.; et al.	2003	Mechanism for the Differential Toxicity of Neonicotinoid Insecticides in the Honey Bee, Apis mellifera. Crop Protection 23(2004): 371-378.	47523404

5. Colony Losses in France

The imidacloprid-based product *Gaucho* was introduced as a seed treatment for sunflowers in France in 1994. Beginning in 1995, French beekeepers reported mysterious losses of colonies in the late summer and fall and blamed *Gaucho* as the causative agent. The hive depopulations were referred to in the press as, "Mad Bee Disease" and "French Bee Malady". In 1999, the French government responded to political pressure from the French beekeeping union and suspended the use of imidacloprid in sunflowers. In 2004 - in the wake of an ongoing, very emotional public discussion in France - the suspension was expanded to include use as a seed treatment in corn (and also to include another chemical, fipronil).

The product suspension was controversial because numerous field studies, including one conducted by the French Government's Bee Pathology Lab, found no adverse effects. (Faucon et al. (2005)).

The general lack of similar problems by beekeepers in other parts of Europe where imidacloprid was also in widespread use as a seed treatment suggested that the cause of the French Bee Malady was something other than imidacloprid. No other European country followed the French lead. Official statements were written by the governments of Germany and the United Kingdom that they were confident that use of imidacloprid as directed would not harm honey bee colonies.

Faucon, J.; Aurieres, C.; Drajnudel, P.; et al.	2005	Experimental Study on the Toxicity of Imidacloprid Given in Syrup to Honeybee (Apis mellifer) Colonies. Pest Management Science 61: 111-125.	47523406

6. Recent European Studies

Research on bee health has continued in France and other European countries after the suspension of imidacloprid from certain uses in France. French studies were published in 2008

(AFSSA reports 2008 - English summaries attached), and a new study was published in Feb 2009 (awaiting translation). A Belgian study was recently published (2008) and a report of bee monitoring in Germany from 2004 to 2008 was also published this year (German Bee Research Institutes, 2009). The conclusion from all these studies is that bees are subject to an increasing number of stressors, including parasitic mites, diseases, nutritional stress and drought. None of these studies have demonstrated any correlation between bee losses and pesticide use.

Author	Date	Citation	MRID
Agence Française de Sécurité des Aliments Sanitaire (Afssa) France	**2008**	**Press Releases Concerning French Bee Studies**	Included with this submission
German Bee Research Institutes	**2009**	**Colony losses monitoring project - Trial years 2004 - 2008 Summary and provisional assessment of results.**	Included with this submission
Nguyen,B.K. Mignon,J. Haubruge,E.	**2008**	**Identification of risk factors implied in honeybee colony collapse in the south part of Belgium. Internet publication**	Included with this submission

Appendix 2

Additional studies for risk assessment

BCS is submitting the following higher tier studies, which may be useful in refining the risk assessment

BIRDS:

Author	Date	Citation	MRID
Wolf, Ch.	**2004**	**Residues in Arthropod Prey of Birds and Mammals After the Application of Confidor® SL 200 (Active Substance Imidacloprid) in a German Pome Fruit Orchard. Unpublished. Bayer Report Number: M-000054-01-1**	Included with this submission
Schabacker, T.	**2007**	**Re-evaluation of the residue study: "Residues in Arthropod Prey of Birds and Mammals After the Application of Confidor® SL 200 (Active Substance Imidacloprid) in a German Pome Fruit Orchard". With regard to the diet of Blue Tits (Parus caeruleus). Unpublished. Bayer Report Number: M-287185-01-1**	Included with this submission

AQUATIC ORGANISMS:

Author	Date	Citation	MRID
Ratte, H. T.; Memmert, U.	**2003**	**Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds. Unpublished. Bayer Report Number: M- 084035-01-1**	Included with this submission
Ratte, H. T.; Memmert, U.	**2005**	**Evaluation of the report - Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds. Unpublished. Bayer Report Number M-251183-01-1**	Included with this submission

Appendix 3

Additional Ecotoxicology Studies Available on Request

(These reports have been submitted by Bayer CropScience in the EU Annex I renewal.)

Non Target Arthropods	Bayer Report #
Schmuck, R. (1991); Effects of an exposure to corn seeds coated with Gaucho FS 600 on the life cycle of rove beetles (Aleochara bilineata) under laboratory conditions	M-007420-01-1
Neumann, P. (1999); Acute effects of imidacloprid (techn.) on larvae of carabid beetles (Poecilus cupreus) under extended laboratory test conditions (0.01 and 0.1 mg/kg)	M-024587-01-1
Fussell, S. (2002); A rate-response laboratory test to determine the effects of Imidacloprid SL 200 on the parasitic wasp, Aphidius rhopalosiphi	M-073272-01-1
Maus, C. (2002); Effects of aged residues of Imidacloprid FS 350 on larvae of carabid beetles (Poecilus cupreus) under extended laboratory test conditions	M-060237-01-1
Bruhnke, C. (2002); Imidacloprid SL 200 - Extended laboratory test on Typhlodromus pyri (munger-cells) exposed on apple tree leaves	M-058820-01-1
Vinall, S. (2001); Toxicity of imidacloprid SL 200 to the parasitic wasp, Aphidius rhopalosiphi, in an extended laboratory test	M-055742-01-1
Maus, C. (2003); Evaluation of the effects of imidacloprid SL 200 on adult carabid beetles (Poecilus cupreus) under extended laboratory test conditions	M-052501-02-1
Staebler, P. (2002); Imidacloprid SL 200: determination of the LR50 (dose response) with the ladybird beetle, Coccinella septempunctata L. (Coleoptera, Coccinellidae) using an extended laboratory test	M-041878-01-1
Staebler, P. (2002); Imidacloprid SL 200: Determination of the LR50 (dose response) with the green lacewing, Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) using an extended laboratory test	M-041301-01-1
Neumann, P. (1999); Acute effects of imidacloprid (techn.) on larvae of carabid beetles (Poecilus cupreus) under extended laboratory test conditions (0,04 - 4 mg/kg)	M-024600-01-1
Neumann, P. (1999); Acute effects of imidacloprid (techn.) on larvae of carabid beetles (Poecilus cupreus) under extended laboratory test conditions	M-020356-02-1
van Stratum, P. (2002); A laboratory dose-response study to evaluate the effect of Imidacloprid SL 200 on survival of the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae)	M-073756-01-1
Bakker, F. M. (1999); An extended laboratory dose-response study to evaluate the effects of imidacloprid tech. on the predaceous mite Hypoaspis aculeifer Canestrini (Acari: Gamasidae)	M-041284-01-1
Keppler, J.; Neumann, P. (2006); Additional statement concerning the high sensitivity of Aphidius rhopalosiphi to imidacloprid based on the comparison with laboratory screening data on target species under special considerations of the off-crop exposure of non-target...	M-287716-01-1
Mead-Briggs, M. A.; Longley, M. (1996); A laboratory evaluation of the effects of the insecticide Confidor SC 200 on the robust pupal life-stage of the parasitic wasp Aphidius rhopalosiphi	M-007395-01-1

Mead-Briggs, M. A. (1995); A laboratory evaluation of the effects of the insecticide Confidor SC 200 on both the adult and robust life stage of the parasitic wasp Aphidius rhopalosiphi	M-007404-01-1
Schmuck, R. (2000); Acute effects of Confidor WG 70 on larvae of carabid beetles (Poecilus cupreus) under laboratory test conditions	M-032974-01-1
Lehmhus, J. (2003); Testing of side effects of Imidacloprid SL 200 on the reproduction of Aphidius rhopalosiphi (De Stefani Perez) (Hymenoptera, Braconidae) under semi-field conditions	M-105258-01-1
Lehmhus, J. (2003); Testing of side effects of Imidacloprid SL 200 on the reproduction of Aphidius rhopalosiphi (De Stefani Perez) (Hymenoptera, Braconidae) under semi-field conditions in Spain	M-102862-01-1
Lehmhus, J. (2003); Testing of side effects of Imidacloprid SL 200 on the reproduction of Aphidius rhopalosiphi (De Stefani Perez) (Hymenoptera, Braconidae) under semi-field conditions with freshly applied and aged residues in Spain	M-102857-01-1
Vinall, S. (2001); An extended laboratory test to determine the effects of Imidacloprid SL 200 on the parasitic wasp, Aphidius rhopalosiphi	M-089347-01-1
Jacobs, G. (2003); Imidacloprid SL 200: Extended laboratory study to evaluate the effects on the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on apple trees- aged residue-	M-086625-01-1
Schuld, M. (2002); Imidacloprid SL 200: Toxicity to the aphid parasitoid, Aphidius rhopalosiphi De Stefani Perez (Hymenoptera, Braconidae) using an extended laboratory test with freshly applied and aged residues	M-075532-01-1
Petto, R. (1993); Effects of Confidor WG 70 on Trichogramma dendrolimi (Hymenoptera, Trichogrammatidae) in apple trees semi field study	M-048258-01-1
Hennig-Gizewski, S. (2000); NTN 33893 SC 200: Acute effects of a repeated spray application on carabid beetles (Poecilus cupreus) under semifield conditions	M-033430-01-1
Bielza, P.; Contreras, J.; Guerrero, M. M.; Izquierdo, J.; Lacasa, A.; Mansanet, V. (2000); Effects of Confidor 20 LS and Nemacur CS on bumblebees pollinating greenhouse tomatoes	M-030222-01-1
Schmuck, R. (1996); Effects of Gaucho WS 70 on introduced (Poecilus cupreus larvae) and naturally occurring populations of carabid beetles under semifield conditions	M-006900-02-1
Schmuck, R. (1992); Effects of Gaucho WS 70 of the life cycle of rove beetles (Aleochara bilineata) under laboratory conditions	M-007364-01-1
Schmuck, R. (1992); Effects of Gaucho WS 70 on carbid larvae (Poecilus cupreus) under laboratory conditions	M-006923-01-1
Heimbach, F. (1990); Toxicity of NTN 33893 (70 WS) coated sugar beet seed to carabid beetles (Poecilus cupreus)	M-007188-01-1
Kemmeter, F. (1999); Imidacloprid (FS 600) (treated corn seeds): Extended laboratory study to evaluate the effects on the lycosid spider, Pardosa spp. (Araneae, Lycosidae)	M-024862-01-1
Schmuck, R. (1992); Effects of Gaucho FS 350 on carabid beetles (Poecilus cupreus) under laboratory conditions	M-007412-01-1
Earthworm	
Heimbach, F. (1986); Acute toxicity of NTN 33893 (techn.) to earth worms	M-006863-01-2

Heimbach, F. (1999); Influence of low concentrations of imidacloprid (tech.) on the reproduction of earthworms (Eisenia fetida)	M-032798-01-1
Soil Microbial Activity	
Blumenstock, I. (1988); Influence of NTN 33893 on the microbial mineralization of nitrogen in soils	M-006964-01-2
Anderson, J. P. E. (1988); Influence of NTN 33893 on the microbial mineralization of carbon in soils	M-006978-01-2
Anderson, J. P. E. (2001); Influence of Confidor (imidacloprid) SL 200 on glucose stimmulated respiration in soils	M-054194-01-1
Anderson, J. P. E. (2001); Influence of Confidor (imidacloprid) SL 200 on the microbial mineralization of nitrogen in soils	M-057539-01-1
Soil -Dwelling Organisms	
Wilhelmy, H. (1999); NTN 33893 - Inhibition of reproduction of collembola (Folsomia candida)	M-031094-01-1
Keppler, J. (1999); Effects of Imidacloprid (a.i.) on viability, parasitization efficacy and reproduction of the entomophagous nematode Steinernema carpocapsae	M-032846-01-1
Lechelt-Kunze, C. (2003); Imidacloprid-olefine: Influence on the reproduction of the collembola Folsomia candida in artificial soil	M-083102-01-1
Lechelt-Kunze, C. (2003); Imidacloprid-nitrosimine: Influence on the reproduction of the collembola Folsomia candida in artifical soil	M-089845-01-1
Bakker, F. M. (1999); An extended laboratory dose-response study to evaluate the effects of imidacloprid tech. on the predaceous mite Hypoaspis aculeifer Canestrini (Acari: Gamasidae)	M-041284-01-1
Anderson, J. P. E. (1999); Influence of imidacloprid (tech.) on growth of pure cultures of a soil fungus, a Phytophthora nicotianae (order Oomycetes), on nutrient medium	M-032870-01-1
Dorgerloh, M. (1999); NTN 33893 - Side effects on the non-target soil fungus, agaricus bisporus ('brown variety')	M-033852-01-1
Anderson, J. P. E. (1999); Influence of imidacloprid (tech.) on growth of pure cultures of a soil fungus, a Suillus granulatus (order Basidiomycetes), on nutrient medium	M-032883-01-1
Anderson, J. P. E. (1999); Influence of imidacloprid (tech.) on growth of pure cultures of a soil fungus, a Mucor circinelloides (order Zygomycetes), on nutrien medium	M-032887-01-1
Anderson, J. P. E. (1999); Influence of imidacloprid (tech.) on growth of pure cultures of a soil fungus, a Paecilomyces marquandii (order Deuteromycetes), on nutrient medium	M-032904-01-1
Friedrich, S. (2002); Imidacloprid SL 200: Effects on the reproduction of the collembola Folsomia candida	M-060021-01-1
Lechelt-Kunze, C. (2003); Imidacloprid SL 200: Effects on soil litter degradation	M-088232-01-1
Meisner, P. (2000); Effects of seed treatments with Gaucho FS 600 Rot on soil litter degradation	M-027712-01-1
Meisner, P. (2002); Effects of seed treatments with Imidacloprid (Gaucho) FS 600 Rot on soil litter degradation	M-032609-02-1

Lechelt-Kunze, C. (2002); Imidacloprid (NTN 33893): Analysis of soil samples of soil litter degradation study E 315 1950-4	M-065419-01-1
Lechelt-Kunze, C. (2003); Imidacloprid FS 600 uncoloured dressed sugar beet seed: Influence on the reproduction of the collembola Folsomia candida in artificial soil	M-083112-01-1
Klein, S.; Meister, A. (2002); Imidacloprid FS 600 ungefärbt: Effects on reproduction of the collembola Folsomia candida in artifical soil	M-060198-01-1

Appendix 4

Imidacloprid Water Monitoring Data

Bayer CropScience Comments on Monitoring Data Available for Imidacloprid

Imidacloprid has been widely used in the USA since registration in 1994. This pesticide is used for the control of sucking insects including rice hoppers, aphids, thrips, and whiteflies, as well as for control of termites, turf insects, soil insects, tree pests and some beetles. With the widespread use of this compound, this pesticide has been included in numerous surface and ground water monitoring efforts at county, state and federal levels. In various monitoring programs, over 12,000 water samples have been analyzed for imidacloprid. Detections of imidacloprid above the limit of quantitation (LOQ) (LOQ ranged between 0.0068 and 0.5 µg/L or ppb) are infrequent even in areas that would be considered vulnerable with regard to potential for movement to surface or ground waters. When samples with notable concentrations are identified, they have generally been found in highly vulnerable areas or were associated with point-source issues.

In no case has levels of imidacloprid in potential drinking waters approached any level of concern for human health. An unofficial maximum contaminant level communicated to Bayer CropScience is 525 µg/L (EPA letter to BCS, 1993). Upon further evaluation of the toxicological endpoint used in this calculation, BCS recalculated a more conservative number of 399 µg/L. More recently, EPA calculated a Drinking Water Level of Concern (DWLOC) in 2003 of 510 µg/L (for children 1 to 2 years old) (Federal Register: June 13, 2003 (Volume 68, Number 114), below which there is reasonable certainty of no human health concern as part of an overall dietary assessment.

From an ecological perspective, results from over 2,000 water samples tested by a range of organizations were examined. The maximum concentration reported in surface water should not pose any significant risk to fresh water, non-target aquatic organisms based on acute toxicity. Imidacloprid has a short half-life in water exposed to sunlight (< 4 hours), so significant concentrations of imidacloprid would not be expected in surface water.

Surface Water Monitoring Data

The USGS (National Water Quality Assessment Program (NAWQA) surface water monitoring program (http://water.usgs.gov/nawqa/data) analyzed 1,948 surface water samples for imidacloprid collected between March 1999 and September 2007. The land uses specified for detections were agricultural, urban, mixed, and other. The maximum concentration of imidacloprid found for any of the specified land uses ranged from 0.24 to 1.32 µg/L, and the median was <LOQ (LOQ = 0.02 µg/L or 0.02 parts per billion) across all samples (note that the limit of quantitation varied in NAWQA analyses, ranging from 0.0068 to 0.4 µg/L).

The California department of Pesticide Regulation (CDPR) monitored surface water for imidacloprid. Between March 2000 and September 2005, ninety-one samples were analyzed for imidacloprid. The LOQ was 0.0068 µg/L. The maximum concentration was 0.2 µg/L, and the median concentration was <LOQ (LOQ = 0.0068 µg/L). The CDPR has also undertaken more focused monitoring, such as that done in coordination with the treatment for control of the glassy-winged sharpshooter in residential areas of Imperial County, CA. No detections of imidacloprid were seen.

As reported in the public comment period, the document *Carpenter, J.L., 2009, Ethoprop and Imidacloprid Survey in Groundwater and Surface Waters of Nevada: Nevada Department of Agriculture. 2007-08* contains results of water monitoring grab samples for five surface water samples. Samples from April 2007 to March 2009 were analyzed for imidacloprid, with a detection limit of 0.5 µg/L. No detects in surface water were noted.

Groundwater Monitoring Data

Data were obtained from the USGS NAWQA groundwater monitoring program (http://water.usgs.gov/ nawqa/data). From June 1999 to March 2007, results from 2,062 sample analyses were included in the NAWQA database. The land uses specified for detections were agricultural, urban, mixed, and other. The maximum concentration of imidacloprid found for any of the specified land uses ranged from 0.11 to 0.93 µg/L. The overall median concentration was at the 0.02 µg/L limit of quantitation (note that the limit of quantitation varied in NAWQA analyses, ranging from 0.0068 to 0.106 µg/L).

Several states monitor for imidacloprid. The Arizona Department of Environmental Quality (ADEQ) maintains a groundwater monitoring program that includes imidacloprid in the analytical methodology. The ADEQ program is limited to two major areas in the state with high pesticide usage and a shallow groundwater aquifer. Imidacloprid products are used only in one of these areas (Yuma). Groundwater samples were taken in the fall of 2006 and in the spring and fall of 2007 and 2008. As of the fall of 2008, twenty wells are sampled and analyzed. The limit of detection for imidacloprid is 0.02 µg/L. A total of 88 samples were analyzed, with 16 samples showing detections of imidacloprid. Imidacloprid detections ranged from 0.05 to 4.1 µg/L with a median concentration at the limit of quantitation (0.02 µg/L).

The California Department of Pesticide Regulation (CDPR) conducts monitoring for chemicals on its ground water protection list, which includes imidacloprid. CDPR monitored for imidacloprid and three metabolites between October and November 2003. Well sites were chosen based on highest use of imidacloprid reported for 1997 through 2001. The reporting limit was 0.05 µg/L for parent imidacloprid, imidacloprid guanidine degrade, and imidacloprid urea degradate and the reporting limit was 0.1 µg/L for the imidacloprid quanidine olefin degradate. Thirty-three domestic, single family wells were sampled and residues were not detected.

The State of Florida conducts a ground water monitoring program on an exceptionally vulnerable area known as the Florida Ridge. Imidacloprid was included in this program with 990 samples analyzed between April 1999 and April 2008. The practical limit of quantitation for imidacloprid analyses was 0.3 µg/L. Here a range of results from < LOQ to 60 µg/L are reflective of the highly vulnerable conditions for the Ridge. Even here, the median concentration for all imidacloprid analyses was less than the limit of detection (LOQ = 0.3 µg/L), and the frequency of imidacloprid detections greater than the limit of quantification was only 7%.

As reported in the public comment period, the document *Carpenter, J.L., 2009, Ethoprop and Imidacloprid Survey in Groundwater and Surface Waters of Nevada: Nevada Department of Agriculture. 2007-08*, reports results of analyses of water monitoring grab samples for 178 ground water samples. No detections of imidacloprid were noted above the limit of quantitation (LOQ = 0.5 µg/L) for samples collected between April 2007 to March 2009.

As reported in the EPA Docket, Suffolk County Department of Health Services on Long Island in New York has an extensive groundwater monitoring program that includes imidacloprid. This is a focused sampling program that emphasizes areas of high use and/or prior detections in groundwater. Overall, imidacloprid detections are rare in drinking water wells and of low frequency in groundwater. Between the years 2000 and 2005 approximately 7,572 groundwater samples were analyzed for imidacloprid. A small number of sampling sites in the county were identified to have point-source issues subjected to improved management. This was not the case for a majority of the wells in the survey between 2000 and 2005, and for these wells there were only 40 samples with detections above an LOQ of 0.2 µg/L with an overall detection frequency of 0.5%.

New York State Department of Environmental Conservation (NYSDEC), as a condition of registration, required Bayer CropScience to conduct a groundwater monitoring study on Long Island for three major use areas of imidacloprid (classified as agricultural, professional and consumer). In this study five groundwater monitoring wells were installed in vegetable production areas, golf course turf areas, and in residential consumer lawns. All areas had known product use in the immediate proximity of the wells. Over a 13-year period the majority of groundwater samples showed no detections of imidacloprid or metabolites. Overall, the detection frequency for imidacloprid was approximately 9.6% in this targeted study, with the majority of detects at trace levels (<0.09 ppb).

Water Monitoring in Canada

The Canadian Water Quality Guideline for imidacloprid cites a number of water monitoring efforts for imidacloprid. (Reference: Environment Canada. 2007. Canadian Water Quality Guidelines for the Protection of Aquatic Life: Imidacloprid. Canadian Environmental Quality Guidelines Canadian Council of Ministers of the Environment.) The majority of samples showed detection of imidacloprid less than the limit of quantitation and in no case has a detection exceeded a US drinking water or environmental protection standard.

CONCLUSIONS

The environmental fate of imidacloprid has been studied intensely and is well understood. Groundwater and surface water monitoring for the compound is extensive, yet occurrence of imidacloprid detections is infrequent, even in areas that would be considered highly vulnerable to leaching. Concentrations of imidacloprid that have been detected (low ppb or trace levels) are generally far below any level of concern for human health or ecological effects. When detects of higher concentration occurred, they have been found in highly vulnerable areas or are associated with point-source issues, In no case has a detection exceeded a US drinking water or environmental protection standard.

Appendix 5

Imidacloprid Mobility Reports

Author	Date	Citation	MRID
Cox et.al.	**1998a**	**Influence of Soil Properties on Sorption – Desorption of Imidacloprid, J. Environ. Sci. Health, B33(2), 123 – 134 (1998), Bayer Document No.: M-023925-01-2; December 31, 1998**	Included with this submission
Cox et.al.	**1998c**	**Changes in Sorption of Imidacloprid with Incubation Time, Soil Science Society of America Journal, Volume 62, No. 2, March – April 1998, Bayer Report # M-023931-01-1, Bayer Document No.: M-023931-01-2; April 30, 1998**	Included with this submission
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